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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,442	02/26/2004	Arthur Ashman	01527/100L635-US1	5006
7278	7590	03/07/2007	EXAMINER	
DARBY & DARBY P.C.			BERMAN, SUSAN W	
P. O. BOX 5257			ART UNIT	
NEW YORK, NY 10150-5257			PAPER NUMBER	
			1711	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/789,442

Applicant(s)

ASHMAN ET AL.

Examiner

Susan W. Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34, 91, 94 and 95 is/are pending in the application.
- 4a) Of the above claim(s) 29-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28, 91, 94 and 95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed 12-14-2006 have been fully considered but they are not persuasive.

It is not agreed, as argued by applicant, that Schaht does not teach polymers having an anhydride linkage. The disclosure of Schaht is not limited to what is exemplified. Schaht clearly teaches, as admitted by applicant, that polyanhydrides are suitable for the biodegradable region (column 6, line 34) and refers to Shastri for specific disclosure of useful polyanhydrides. The disadvantages from using polyanhydrides taught by Schaht do not preclude the usefulness of polyanhydrides in the absence of therapeutic agents having reactivity with the anhydride linkage. Furthermore, Schaht teaches that this disadvantage is overcome by indirectly incorporating therapeutic agents having reactivity with the anhydride linkage. Also, this teaching suggests that polyanhydrides can be used with any therapeutic agents not having reactivity with the anhydride linkage.

Applicant argues that the instant invention has new and useful properties compared with the Schaht polymers. This argument is not persuasive because the allegations are not supported by comparative data to show unexpected or significantly improved results. Examples 11-12 provide data with respect to mechanical strength as shown by compressive yield strain, compressive yield strength, and crushing load. However, there is no comparative data with respect to the closest prior art teaching, i.e. polymers as taught by Schaht containing polyanhydrides to provide a biodegradable region.

With respect to Anseth et al in view of Schaht: addition of a bone substitute is considered at least to be an addition of a "material as needed for a particular implant application", as

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suggested by Anseth et al, and is also considered to be an addition of a filler or reinforcement material. The teaching of "other materials as needed for a particular implant application" is not considered to be vague since it refers to a "particular implant application" and is particularly relevant to the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 15-28, 91, 94 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schacht (6,933,328). Schacht discloses a composition comprising a crosslinkable prepolymer, a polyester, polyorthoester or polyacetal, and a mineral biologically active component for a bone implant or cement or a dental material. The crosslinkable multifunctional prepolymer in the second embodiment is preferably a polyester (column 3, line 60, to column 4, line 9). The polymerizable groups are ethylenic or acetylenic unsaturations (column 7, line 62, to column 8, line 7). Polymerization initiators, including photoinitiators and redox initiators, and a dual curing system are taught in column 12, lines 30-65. Compositions containing bone substitutes are taught in Examples 7 and 21. See Example 15, wherein a hydroxy carbonic acid oligomer is reacted with methacrylic anhydride followed by reaction of the carbonic acid group to provide an N-hydroxy-succinimidyl end group which is coupled to an oligopeptide. Example 21 discloses a combination of bone allograft and curable composite wherein the curable composition is

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placed on top of an allograft filling. The difference from the instantly claimed invention is that the bone allograft and curable composition are not mixed or applied as a mixture.

It would have been obvious to one skilled in the art at the time of the invention to mix the bone allograft material taught by Schacht with the curable composition taught by Schacht instead of applying the components in layers. The reason is that Schacht teaches that various therapeutic agents, diagnostic agents and/or porosity forming agents can be added to the curable compositions. The synthetic bone allograft is considered to be a therapeutic agent. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation that the bone allograft in a mixture would have been secured in place by curing the curable composition. With respect to claims 25-28, the compositions taught by Schacht would be expected to provide the recited properties since the components taught by Schacht correspond to the components set forth in claim 1 or claim 24.

Claims 5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schacht (6,933,328), as applied to claims 1-4, 15-28, 91, 94 and 95 above, and further in view of Shastri et al (5,837,752) or Anseth et al (5,902,599). The disclosure of Schacht is discussed herein above. The difference from the instantly claimed invention is that Schacht does not specifically teach the methacrylic acid dianhydrides set forth in instant claims 5-14.

Shastri et al disclose semi-interpenetrating polymer networks comprising a linear hydrophobic degradable polymer and monomers or macromers including an anhydride linkage. The compositions can include inorganic salts and proteinaceous materials (column 3, lines 21-34 and lines 51-59). The macromers containing ethylenically unsaturated polymerizable groups can be obtained from unsaturated dicarboxylic acids that provide water-soluble blocks.

It would have been obvious to one skilled in the art at the time of the invention to employ the ethylenically unsaturated macromer taught by Shastri et al in an analogous composition for repairing bones as the crosslinkable prepolymer in the composition containing a bone allograft suggested by

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Schacht. Schacht provides motivation by teaching that the crosslinkable prepolymers are polyesters comprising polymerizable end groups and a biodegradable region from a poly- α -hydroxy acid or a polyanhydride or mixtures thereof (column 6, lines 29-35). Shastri et al provide motivation by teaching that the crosslinkable macromers can be polymerized to provide a porous polymer network and that they can be polymerized ex vivo or in situ to replace or repair bone. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of providing a useful compositions for bone repair or replacement.

Claims 1-28, 91, 94 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anseth et al (5,902,599) in view of Schacht. Anseth et al disclose biodegradable polymer networks obtained by polymerizing anhydride prepolymers including unsaturated crosslinking groups. Methacrylic acid dianhydrides of diacids such as sebacic acid or 1,3-bis(p-carboxyphenoxy)-hexane are disclosed. Anseth et al teach that the prepolymers can be combined with fillers, reinforcing materials and/or other materials needed for a particular implant (column 7, lines 53-58). The disclosure of Schacht is discussed herein above. Anseth et al do not specifically disclose bone substitute materials as additives in the disclosed compositions.

It would have been obvious to one skilled in the art at the time of the invention to employ the bone allograft taught by Schacht as a material needed for a particular implant in combination with the crosslinkable anhydride prepolymers disclosed by Anseth et al. Anseth et al provide motivation by teaching that such materials can be added to the disclosed prepolymers. Schacht provides motivation by teaching that bone allograft can be combined with an analogous compositions comprising analogous crosslinkable polyester prepolymers.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SB
2/22/07



Susan W Berman
Primary Examiner
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